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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/847,061	061 05/01/2001		Guang Yang	P-092-R	4558
21186	7590	12/12/2003		EXAMINER	
SCHWEGN P.O. BOX 29		NDBERG, WOES	LIU, SAMUEL W		
MINNEAPO		55402	ART UNIT	PAPER NUMBER	
				1653	

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		Application No.	Applicant(s)				
		09/847,061	YANG ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Samuel W Liu	1653				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SH THE I - Exter after - If the - If NC - Failu - Any I	ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication, period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by state eply received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply be ti eply within the statutory minimum of thirty (30) da od will apply and will expire SIX (6) MONTHS from tute, cause the application to become ABANDON!	mely filed ys will be considered timely. n the mailing date of this communication. ED (35 U.S.C. § 133).				
1)⊠	Responsive to communication(s) filed on <u>07</u>	October 2002 and 07 October 200	<u>03</u> .				
2a) <u></u>	This action is <b>FINAL</b> . 2b)⊠ Th	is action is non-final.					
3)[	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
5)□ 6)⊠ 7)⊠	Claim(s) 7,13,14 and 16-28 is/are pending in the application.  4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) 7,13,14 and 18-28 is/are rejected.  Claim(s) 20 is/are objected to.  Claim(s) are subject to restriction and/or election requirement.						
	ion Papers	,					
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
* \$ 13) \( \times \) \( \times	Acknowledgment is made of a claim for fore  All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure See the attached detailed Office action for a li acknowledgment is made of a claim for dome ince a specific reference was included in the 7 CFR 1.78.  The translation of the foreign language packnowledgment is made of a claim for dome eference was included in the first sentence of	ents have been received. ents have been received in Applicariority documents have been received in Applicariority documents have been received (PCT Rule 17.2(a)). ist of the certified copies not receivestic priority under 35 U.S.C. § 1196 first sentence of the specification of provisional application has been restic priority under 35 U.S.C. §§ 120	tion No  red in this National Stage  ed.  (e) (to a provisional application)  or in an Application Data Sheet.  ceived.  2 and/or 121 since a specific				
Attachmen							
2) D Notic	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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## **DETAILED ACTION**

Status of the claims

Claims 7, 13-14 and 16-28 are pending.

Applicants' amendment filed 7 October 2003, which amends claims 7 and 13-14, cancels claims 1-6, 8-12 and 15, and adds claims 18-28, has been entered.

#### Election/Restrictions

Applicant's election (see the response filed 7 October 2003) of Group I, claims (pending) 7 and 13-14 with traverse is acknowledged. The traversal is on the ground(s) that search can be done without serious burden to Examiner, and Groups I and II are classified in the common classes and subclasses not separable. In this regard, examiner has quoted the following statement:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend** from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Of the above mentioned pending claims, claims 16-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions.

Thus, the elected claims 7, 13-14 and 18-28 are under examination to the extent that they are drawn to the elected invention.

## IDS

The references lists in Information disclosure Statements filed 10 January 2002, 5
February 2002, and 6 May 2002 have been received. The references recited in the PTO 1449
Forms of submitted the IDS documents have been considered by Examiner.

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Specification/claim Objections

The disclosure is objected to because of the following informalities:

In page 12, line 11, "formula –CH2" should be changed to "formula –CH<sub>2</sub>"; the similar

changed should be made throughout the specification.

In claim 20, after "-NH-" add "group".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 7, as written, do not distinguish the claimed glycopeptide from naturally existing products. The claims do not particularly point out any differences indicating the hand of man. In the absence of the hand of man, the claimed products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, *e.g.*, by insertion of "isolated" or "purified" as disclosed on example 1 wherein indicate the disclosed composition is prepared through chemical modification. See MPEP 2105.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

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Claims 7, 13-14 and 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in the recitation "x is 1 or 2"; where in the claim "x" refers to? Also, claim 7 is unclear as to "or a pharmaceutical acceptable salt, stereoisomer, or prodrug thereof"; is the claimed glycopeptide is a pharmaceutical acceptable salt, stereoisomer, or prodrug? Note that pharmaceutical acceptable salt is not active composition, prodrug is an inactive precursor of a drug, converted into its active form in the body by normal metabolic processes, and that stereoisomer. What is stereoisomer respective to the claimed glycopeptide? Claim 7 does not make it clear that what compound of stereoisomer is. The dependent claims are also rejected.

### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

KAREN COCHRANE CAPLSON, PH.D

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Samuel W. Liu, Ph.D.

SWL

November 21, 2003